1. I have reviewed your guidelines and, while one by one they seem reasonable, (except 5.3 below) your group has NOT consdered the cumulative burden it has placed on IRBs.

2. Even in a practical sense can the IRB in fact do such a wide ranging job with responsibilities and onerous consequences should it fail/ overlook details of review specifically because of the widened resposibility profile? Tasks just accumulate.

3. I have concerns with 5.3 below. While it aims at industry, it does not deal with NIH funded investigators whose research, renewals, funding, academic promotion etc depend on completion of the research, and the study.

4. I do not advocate adding this to the list. I suggest that in an effort to make our system 100% safe and "informative", the burden to give "truly informed consent" actually fails at the level of the patient. This is because a) it makes the documents which they must read more like an arcane, legal text requiring expertise to interpret, b) necesitates an 'impartial' individual to explain and avoid coercion, c) presumes the need for this impartial individual because there is something wrong, and d) finally the patient is turned off to the research or blankly signing a document they do not understand.
Are the proposed, additional guidelines a solution to help the vast majority of patients who come to us for help, rather than an overreaction to the headlines of the outliers? I am not sure.

5. If a financial conflict of interest on the part of the Institution and/or Clinical Investigator has not been or cannot be eliminated, what the financial arrangement is and how that conflict is being managed should be disclosed in the Consent document. The document should explain what additional protections have been put in place. An IRB should consider taking special measures to modify the consent process when a potential financial conflicts exists. These could include having a non-biased third party obtain Consent, especially when potential conflicts could influence the tone or presentation of information during the consent process.

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